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| 10/594,661 | 08/09/2007 | Ken Kato | MUR-050-USA-PCT | 1645 |
| 27955 | 7590 | 12/01/2009 | EXAMINER | |
| TOWNSEND & BANTA c/o PORTFOLIO IP PO BOX 52050 MINNEAPOLIS, MN 55402 | | | KENNEDY, NICOLETTA | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/594,661 | Applicant(s) KATO ET AL. | |
| | Examiner Nicoletta Kennedy | Art Unit 1611 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/11/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-4 are pending. Claims 5-7 are withdrawn.

Response to Amendment

1. Newly submitted claims 5-7 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly submitted claims claim a method for decreasing transepidermal water loss. The new claims would require a different search strategy and would constitute a search burden.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 5-7 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawn Rejections

2. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Greff et al. (FR 2692781) are withdrawn in view of Applicants' amendments.

Response to Arguments

1. Applicants' arguments with regard to claims 1-2 are noted but are not found to be persuasive in view of Applicants' amendments.

Applicants' arguments with regard to claim 3 have been considered but are not found to be persuasive. Applicants argue that Msika et al. in view of Nieuwenhuizen et al. fail to teach that the food containing sphingomyelin decreases transepidermal water loss of the skin and thus results in beautifying effects thereto. However, in claim 3, the

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claim preamble claims a skin beautifier. During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, Msika et al. in view of Nieuwenhuizen et al. teach a food composition comprising sphingomyelin (Msika et al., column 5, lines 48-55; column 13, lines 1-13 and 56-58). There is no evidence that the instant claim has a structural difference from the drink or feed taught by Msika et al. in view of Nieuwenhuizen et al. and thus "skin beautifier" is an intended use not afforded patentable weight.

Even if "skin beautifier" is afforded patentable weight, the product taught by Msika et al. in view of Nieuwenhuizen et al. would beautify skin.

Therefore, it is the Examiner's position that the Msika et al. in view of Nieuwenhuizen et al. have produced the same skin beautifying effect based on the oral administration of a food with sphingomyelin as the effective ingredient as the instant claims. One of ordinary skill in the art would reasonably conclude that Msika et al. in view of Nieuwenhuizen et al.'s food also possesses the same structural and functional properties as those of the feed claimed and, therefore, it appears that Msika et al. in view of Nieuwenhuizen et al. would have produced a feed with skin beautifying effects that are identical to the claimed feed. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed feed with the feed of Msika

et al. in view of Nieuwenhuizen et al. the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed feed and the feed of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Similarly, regarding claim 4, Applicants' argue that Nieuwenhuizen et al. in view of Greff et al. fail to teach that the food containing sphingomyelin decreases transepidermal water loss of the skin and thus results in beautifying effects thereto. However, in claim 4, the claim preamble claims a skin beautifier. During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, Nieuwenhuizen et al. in view of Greff et al. teach a food composition comprising sphingomyelin (Msika et al., column 5, lines 48-55; column 13, lines 1-13 and 56-58). There is no evidence that the instant claim has a structural difference from the drink or feed taught by Nieuwenhuizen et al. in view of Greff et al. and thus "skin beautifier" is an intended use not afforded patentable weight.

Even if "skin beautifier" is afforded patentable weight, the product taught by Nieuwenhuizen et al. in view of Greff et al. would beautify skin.

Therefore, it is the Examiner's position that the Nieuwenhuizen et al. in view of Greff et al. have produced the same skin beautifying effect based on the oral administration of a food with sphingomyelin as the effective ingredient as the instant claims. One of ordinary skill in the art would reasonably conclude that Nieuwenhuizen et al. in view of Greff et al.'s food also possesses the same structural and functional properties as those of the feed claimed and, therefore, it appears that Nieuwenhuizen et al. in view of Greff et al. would have produced a feed with skin beautifying effects that are identical to the claimed feed. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed feed with the feed of Nieuwenhuizen et al. in view of Greff et al. the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed feed and the feed of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

New Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Yukihiro et al. (JP 2001-158736) (pub. June 12, 2001).

Regarding claims 1-2, Yukhiro et al. teach a feed comprising sphingomyelin (translated detailed description, paras. 0001, 0005, 0008 and 0012). The sphingomyelin may be derived from cow's milk (para. 0007-0008 and 0012). The drink or feed was administered orally to human patients (para. 0025 and 0035).

Regarding claims 1-2, the claim preamble claims a skin beautifier. During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, Yukhiro et al. teach a composition comprising sphingomyelin. The sphingomyelin is blended into an eating-and-drinking article or feed (para. 0008). There is no evidence that the instant claim has a structural difference from the drink or feed taught by Yukihuro et al. and thus "skin beautifier" is an intended use not afforded patentable weight. Even if "skin beautifier" is afforded patentable weight, the product taught by Yukihuro et al. would inherently beautify skin.

Therefore, it is the Examiner's position that Yukihuro et al. have produced the same skin beautifying effect based on the oral administration of a feed with sphingomyelin as the effective ingredient as the instant claims. One of ordinary skill in the art would reasonably conclude that Yukihuro et al.'s feed also possesses the same structural and functional properties as those of the feed claimed and, therefore, it appears that Yukihuro et al. would have produced a feed with skin beautifying effects

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that are identical to the claimed feed. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed feed with the feed of Yukihiro et al., the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed feed and the feed of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Conclusion

No claims are allowed.

New grounds of rejection were necessitated in this Office Action only because of Applicants' amendments. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 36 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./

Examiner, Art Unit 1611

/David J Blanchard/

Primary Examiner, Art Unit 1643